Hospira

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Hospira at a glance

Hospira

The World's Leading Provider of Injectable Drugs and Infusion Technologies

- **Market leadership positions in:**
  - generic injectable pharmaceuticals globally
  - biosimilars in Europe, Australia, Canada and soon in the U.S. and Brazil
  - **Hospira is the world's leading provider of injectable drugs and infusion technologies, and a global leader in biosimilars.**
- **80 years experience; public independent company since 2004**
- **HQ in Lake Forest, IL**
- **~19,000 employees**
- **Pfizer acquisition of Hospira announced February 2015**

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Global overview as of March 2014

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The Promise of Biosimilars

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Biologics can treat patients with cancer, chronic kidney diseases and auto-immune diseases, such as rheumatoid arthritis and inflammatory bowel disease.

Without competition, reference biologics can be very expensive drugs, costing as much as $100,000 a year, or even more.

DUE TO THEIR LOWER COSTS, INTRODUCTION OF BIOSIMILARS IN THE U.S. IS EXPECTED TO CREATE INCREASED ACCESSIBILITY AND COST SAVINGS. ACCORDING TO A RECENT RAND STUDY, BIOSIMILARS ARE ANTICIPATED TO CUT SPENDING ON BIOLOGICS BY $44B IN THE U.S. OVER THE NEXT DECADE.

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Hospira has 7+ years market experience in the EU with a multi-therapeutic biosimilar portfolio and 3+ years experience in Australia with Nivestim™

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retacrit epoetin zeta

Hospira's 1st biosimilar, Retacrit™ *(referenced to Eprex-epotein alfa),* received EU approval in Dec 2007

INFLECTRA INFLIXIMAB 1st Biosimilar MAb

Our 3rd biosimilar, Inflectra™ *(referenced to Remicade-infliximab),* received EU approval in Sept 2013 and Canada approval in 2014

2007 2010 2013

nivestim™ filgrastim

Our second biosimilar, Nivestim™ *(referenced to Neupogen-filgrastim),* received EU approval in June 2010 and AU approval in September 2010.

Nivestim™ was Australia's first biosimilar filgrastim.

Uptake of biosimilars in EU markets varies by country, primarily driven by:

- **prescribers** who want safe and effective products, and
- **payers** who want cost savings with increased competition

Our goal is to provide high quality products at cost-competitive prices thereby providing healthcare savings and improving patient access

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The Future Opportunity of Biosimilars

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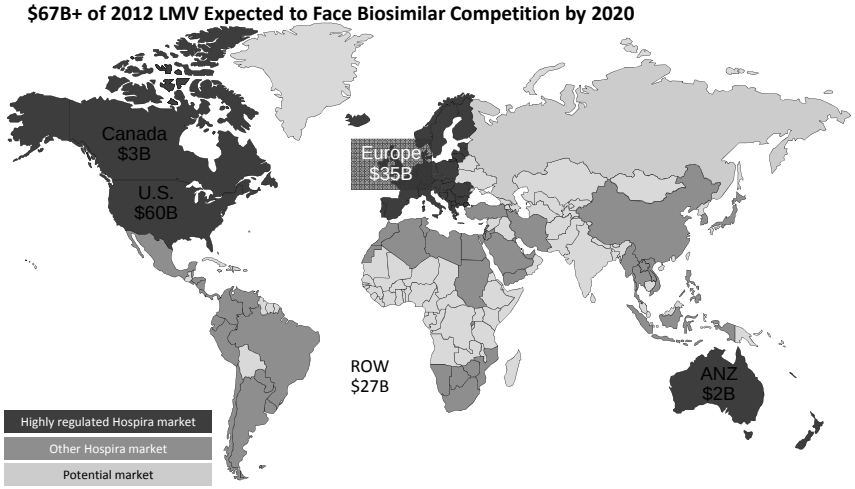
Current global biologics market: $127B, Growth rate: ~9%
$67B+ of 2012 LMV Expected to Face Biosimilar Competition by 2020



*LMV: local market value. LMV is not a forecast of Hospira's expected net sales. ROW: rest of world
Source: Excludes Vaccines; Source PharmaView, Decision Resources, 2013, Regional Figures modified from DataMonitor, 2012.

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Biosimilars in the U.S. Market: Critical Success Factors:

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Naming

Hospira believes that naming must be simple and intuitive to be effective.

Same INN

Appropriate Coding and Reimbursement

Hospira supports a thoughtful science-based approach setting unique reimbursement codes for biosimilars

Extrapolation and Increased Awareness

Hospira supports a science-based extrapolation approval process for biosimilars

We need to increase Patient and Provider Awareness

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Naming: The Case for Same INN

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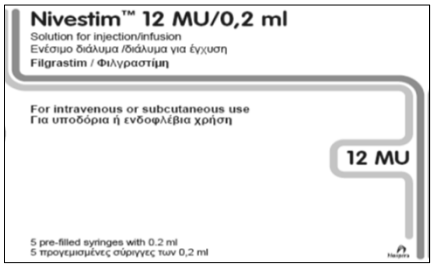
Hospira believes that naming must be simple and intuitive to be effective. We also believe that patient safety and accessibility are best ensured when biosimilars share the same "nonproprietary" name with the original biologic.

Based on our experience, adding more complexity to current naming is **NOT** recommended as it will increase confusion for physicians, pharmacists and patients.

Biosimilar products have been in the European market since 2006/2007 and have had the same INN **with pharmacovigilance maintained without a unique INN.**



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Appropriate Coding and Reimbursement to Ensure a Sustainable Marketplace

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- Private insurance often follows Medicare's lead, so Medicare in practice sets reimbursement policy for the U.S. healthcare system broadly.
- CMS, the agency that administers Medicare, assigns reimbursement codes for medical procedures and medicines.
- The type of code applied to most biologics, which are often injected in a doctor's office or a hospital, is called a J-Code.
- Biosimilars are unique, but CMS may be considering a detrimental "one size fits all" approach to reimbursement.

Grouping all biosimilars together under a single J-Code or blended reimbursement would create a disincentive to invest in this crucial area of medicine and would not foster a sustainable and vibrant market for Biosimilars.

- Inadequate reimbursement will erode the market that is needed to spur competition in this area, as manufacturers will have no incentive to invest in quality.
- Without competition, patients may not have sufficient access to biosimilars in a range of therapeutic areas.

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Extrapolation: The Key to Biosimilar Success

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- **Biosimilars are similar copies of approved biologics,** but available at a 20-30+% discount because the FDA requires fewer clinical trials to be performed as long as the safety and efficacy of the biosimilar has been established and is comparable to the biologic.
- **To ensure the safety and efficacy of biosimilars, biosimilar product development requires:**
  - **Comprehensive bioanalytical characterization supported by comparative nonclinical and clinical data, this is the concept of the "totality of evidence."**

HOSPIRA supports a science-based extrapolation approval process for biosimilars and is committed to providing access to safe, effective and high-quality medicines to patients at a more affordable cost.

FDA should consider extending approval of all the disease indications for the biologic to the biosimilars without clinical trials on a case-by-case basis, if **biosimilarity has been demonstrated in the comparative studies**.

By cutting down on the number of clinical trials, extrapolation of biosimilars will help to **reduce healthcare costs**, while providing the same **high-quality medication**.

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Biosimilars Are Not Generics

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Biosimilars are far more complex. Unlike typical generic drugs made from synthetic chemicals, biologic drugs are produced from a living organism.

Biosimilars take longer and cost more to develop. Biosimilars are much more complex products that require more investment to create and more testing to gain regulatory approval. It typically costs $100 million to $200 million and requires eight to 10 years to develop a biosimilar product.

Generics create greater per-unit reductions in costs. Based on Hospira's experience in Europe and Australia, we expect biosimilars to bring initial savings of approximately 20 to 30 percent, versus initial savings of 75 percent for generics BUT, given the total revenue of each biologic drug, the absolute saving will be massive

Biosimilar Manufacturers are working together. Hospira is proud to be a member of a coalition of 11 leading companies involved in the development and manufacturing of biopharmaceuticals and "biosimilar" medicines -- The Biosimilars Forum.

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Conclusion

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Bringing biosimilars to the United States is the next major step toward reducing costs for the healthcare system and improving patient access to high-quality biologic drugs.

Biologics are 7 out of the top 10 highest selling drugs in the U.S. with treatments that can cost $100,000 or more per year for a patient.

Importantly, Biosimilars have been widely and safely used in the EU since 2006 and continue to make progress there and in other markets.

Biosimilars offer great promise to American patients, providers and payers, however the keys to success in the U.S. are:

1. **Naming**
2. **Appropriate Coding and Reimbursement**
3. **Extrapolation and Awareness**

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